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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,105	09/17/2003	Nadine Michele Sullivan	TDS-125US	6147

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EXAMINER	
BRADRICK, THOMAS DALE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,105	SULLIVAN ET AL.	
	Examiner	Art Unit	
	Thomas D. Bradrick	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *13-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *31 December 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-32 are pending. Claims 1-12 are being examined on the merits. Claims 13-32 are withdrawn from consideration as being drawn to a non-elected invention.

Election was made **without** traverse in the reply filed on 19 August 2005.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the vial headspace **20** (Fig. 1) as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required

corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: what should presumably be the chemical name gallocyanide on p.5, l. 11 and p. 9, l. 14 is misspelled.

Appropriate correction is required.

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms that are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: the description of of Fig. 5 (p. 12, l. 27 to p. 13, l. 7). Applicant refers to unspecified samples being taken from hitherto unmentioned herds of animals, resulting in percentages of false positives of some test that is completely unspecified. The description is lacking in sufficient detail to enable the reader to understand what is being carried out in this example.

Claim Objections

Claim 8 is objected to because of the following informalities: what should presumably be the chemical name gallocyanide is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eden *et al.* [IDS] in view of Lancaster *et al.* [IDS].

Claims 1-12 are drawn to a method of stabilizing the output signal of a system that detects microbiological growth in a sealed container, comprising the steps of i) providing a sealed container containing a culture broth, the sample and at least one poising agent, ii) monitoring pressure changes within the headspace of the sealed sample container, and iii) indicating a presence of microbiological growth within the sealed sample container as a function of the change in the headspace pressure (claim 1). The method is further specified to comprise providing a pair of coupled poising agents (claim 2) selected from the group consisting essentially of ferricyanide/ferrocyanide and ferrous/ferric (claim 3), specifically

ferricyanide/ferrocyanide (claim 4) whose concentration is within the range of 50 μM to 1 mM (claim 5) and ratio is between 1:4 and 4:1 (claim 6). The methods of claim 2 is further specified to include the step of providing a second poising agent that is a reversible oxidation-reduction indicator (claim 7) that is selected from the group consisting essentially of methylene blue, toluidine blue, azure I and gallocyanine (claim 8) and adding at least two reagent mixtures (claim 11) comprising at least one growth supplement and one antibiotic supplement (claim 12). Similarly, the method of claim 1 is further specified to comprise adding at least two reagent mixtures (claim 9) comprising at least one growth supplement and one antibiotic supplement (claim 10).

Eden *et al.* [IDS] disclose a method for detecting microbiological growth in a sealed sample chamber, in which the container headspace pressure is monitored as an indicator of microbiological growth (Abstract). Eden *et al.* [IDS] do not disclose the inclusion of poising or redox buffering agents in the culture medium.

Lancaster *et al.* [IDS] disclose the use of poising agents or redox salts to inhibit autoreduction in microbial cultures without substantially affecting the desired reduction that takes place as a result of cellular metabolism [col. 3, l. 58 ff]. The addition of coupled pairs of reduced and oxidized salts or agents, such as ferricyanide/ferrocyanide and ferric/ferrous salts [col. 4, l. 10 ff], with a concentration range of 50 μM to 1 mM and a ferricyanide/ferrocyanide ratio of 1:4 to 4:1 [col. 7, l. 15 ff], is preferred. In addition to the coupled poising agents, the growth media preferably includes a second poising agent that is also a reversible oxidation/reduction indicator. Suitable second poising agents include methylene blue (which has been found to stabilize the oxidation-

reduction potential of the medium), toluidine blue, azure I and gallocyanide [col. 7, l. 21 ff]. A suitable growth medium is used that may be supplemented with fetal calf serum, Hank's Modified Eagle Medium and Dulbecco's Modified Eagle Medium [col. 6, l. 9 ff], and include antibiotics [Tables II and III].

In light of the preceding, one of ordinary skill in the art would have been motivated to make the substitution of the cell culture medium as described by Lancaster *et al.* [IDS] for that in the method of the primary reference (Eden *et al.* [IDS]) in order to obtain, with a reasonable expectation of success, the method as disclosed in the instant application. This would constitute the substitution of an art-accepted equivalent and have the obvious advantage of reducing oxidative stress on the micro-organisms being cultured. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, claims 1-12 are properly rejected under 35 U.S.C. § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Bradrick whose telephone number is (571) 272-8139. The examiner can normally be reached Monday through Friday between 8:30 a.m. and 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thomas Bradrick
Patent Examiner
Art Unit 1651

SANDRA E. SAUCIER
PRIMARY EXAMINER